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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/18/2003

TC

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/738,599

Applicant(s)

Nolan et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jan 30, 2003

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 30-33 and 35-67 is/are pending in the application.

4a) Of the above, claim(s) 35, 36, and 46-66 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 30-33, 37-44, and 67 is/are rejected.

7) Claim(s) 45 is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 01/30/03 (paper no. 13) in response to the non-final Office Action mailed 09/30/02 (paper no. 11). With this, Applicants have amended the specification.

Status of Claims

2) Claims 1-29 and 34 have been canceled via the amendment filed 01/30/03.
Claims 30-33, 35-37 and 43-45 have been amended via the amendment filed 01/30/03.
New claim 67 has been added via the amendment filed 01/30/03.
Claims 30-33 and 35-67 are pending.
Claims 30-33, 37-45 and 67 are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

5) The objection to the specification made in paragraph 6 of the Office Action mailed 09/30/02 (paper no. 11) is withdrawn in light of Applicants' amendments to the specification.

Rejection(s) Moot

6) The rejection of claim 34 made in paragraph 7 of the Office Action mailed 09/30/02 (paper no. 11) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of the U.S. Patent 6,087,128, is moot in light of Applicants' cancellation of the claim.

7) The rejection of claim 34 made in paragraphs 9(b) and 9(e) of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

8) The rejection of claim 34 made in paragraph 11 of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 102(a) as being anticipated by GenEmbl Accession AF042279, GI:5305230, submitted 01/10/1998 (Horne, Nolan, Giddings and Pfaff), is moot in light of Applicants' cancellation of the claim.

9) The rejection of claim 34 made in paragraph 12 of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 102(b) as being anticipated by Barondess *et al.* (*Nature* 344: 871-874, 1990 - Applicants' IDS) (Barondess, 1990), or Chuba *et al.* (*Mol. Gen. Genet.* 216: 287-292, 1989 - Applicants' IDS), is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

10) The rejection of claim 37 made in paragraph 8 of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 101 as being directed to a non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claim 30 made in paragraph 9(a) of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claims 31, 33, 43, 44 and 45 made in paragraph 9(b) of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

13) The rejection of claim 32 made in paragraph 9(c) of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

14) The rejection of claim 33 made in paragraph 9(d) of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

15) The rejection of claims 37 and 43 made in paragraph 9(f) of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

16) The rejection of claim 43 made in paragraphs 9(h) and 9(i) of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn

in light of Applicants' amendment to the claim.

17) The rejection of claims 38-45 made in paragraph 9(j) of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

18) The rejection of claim 30 made in paragraph 11 of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 102(a) as being anticipated by GenEmbl Accession AF042279, GI:5305230, submitted 01/10/1998 (Horne, Nolan, Giddings and Pfaff), is withdrawn in light of Applicants' submission of a Declaration (*Katz*) under 37 C.F.R § 1.132 excluding co-authors Giddings and Pfaff as 'another'.

19) The rejection of claims 37-40 and 43 made in paragraph 12 of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 102(b) as being anticipated by Barondess *et al.* (*Nature* 344: 871-874, 1990 - Applicants' IDS) (Barondess, 1990), or Chuba *et al.* (*Mol. Gen. Genet.* 216: 287-292, 1989 - Applicants' IDS), is withdrawn. A modified rejection is made below.

Rejection(s) Maintained

20) The rejection of claim 42 made in paragraph 9(g) of the Office Action mailed 09/30/02 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein. It is noted that claim 42 has not been amended.

21) The rejection of claims 30-33 made in paragraph 7 of the Office Action mailed 09/30/02 (paper no. 11) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of the U.S. Patent 6,087,128, is maintained for reasons set forth therein. It is noted that Applicants have agreed to provide an appropriate response upon indication of allowable subject matter.

22) The rejection of claims 37-44 made in paragraph 7 of the Office Action mailed 09/30/02 (paper no. 11) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of the U.S. Patent 6,087,128, is maintained for reasons set forth therein. It is noted that Applicants have agreed to provide an appropriate response upon indication of allowable subject matter.

New claim 67 is now included in this rejection.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office Action. The new rejections are necessitated by Applicants' amendments to the claims and/or the base claim and/or the submission of new claims.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

23) Claim 67 is rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 67 is vague and confusing in the recitation "wherein the immunogenic composition generates an antibody response when administered to a subject", because it is unclear to what the antibody response is generated to: nucleic acid molecule, its subunit or its fragment, or the product encoded by the nucleic acid molecule, its subunit or its fragment?

Rejection(s) under 35 U.S.C § 102

24) Claims 37-40, 43 and 67 are rejected under 35 U.S.C § 102(b) as being anticipated by Barondess *et al.* (*Nature* 344: 871-874, 1990 - Applicants' IDS) (Barondess, 1990), or Chuba *et al.* (*Mol. Gen. Genet.* 216: 287-292, 1989 - Applicants' IDS) as evidenced by Harlow *et al.* (*In: Antibodies: A laboratory Manual*. Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988).

It is noted that the nucleic acid molecule, an immunogenic fragment, or an immunogenic subunit thereof claimed in claim 37 encompasses non-isolated nucleic acid molecules, fragments and subunits, and therefore the prior art plasmids, cells or bacteria comprising the nucleic acid molecule, a fragment or a subunit thereof as recited, would anticipate the claimed product in addition to the isolated products of the prior art.

Chuba *et al.* or Barondess *et al.* (1990) disclosed a nucleic acid molecule comprising several long stretches of nucleotides showing 100% sequence identity with nucleotides 73 to 309 of SEQ ID NO: 22, plasmids, vectors, phages and host cells comprising the same. See the sequence search reports attached to the Office Action mailed 09/30/02 (paper no. 11) and the entire reference. Barondess *et al.* (1990) taught a *bor* gene sequence which encodes an envelope protein, gene fusions, fragments thereof, and fusions expressed in lysogens (see pages 871 and 872; and Fig 1 and Figure 1 legend). The fusion fragments were subcloned and sequenced. The cells are contained in PBS (i.e., a pharmaceutically acceptable carrier). Similarly, Chuba *et al.* taught plasmids and *E. coli*

strains carrying the nucleic acid molecule. The cells are contained in PBS, i.e., a pharmaceutically acceptable carrier (see Materials and Methods). The long fragments of Barondes's or Chuba's nucleic acid molecule are expected to encode a fragment of a polypeptide that is long enough to serve as an immunogenic fragment or immunogenic subunit. For instance, the 35 nucleotide base-long fragment contained in Barondes's nucleic acid molecule, or the 146 nucleotide base-long fragment contained in Chuba's nucleic acid molecule would inherently encode a polypeptide fragment that is at least 6 amino acid-long peptide of a full length protein, which is recognized in the art to be long enough to be immunogenic to induce an antibody response in a subject (see page 76 of Harlow *et al.*), absent evidence to the contrary. It is further inherent that a sufficiently long polypeptide fragment or subunit is expressed by the prior art DNA molecule which polypeptide fragment would be immunogenic and generate an antibody response in a subject. The functional limitation, "immunogenic" or 'generates an antibody response', on which the prior art references are silent, is considered to be an inherent property of the prior art product. Where the only difference between claimed product and the prior art product is recited in the functional language, i.e., by what it does rather than what it is, it is incumbent upon Applicants, when challenged by the USPTO, to demonstrate that the prior art product does not actually possess those characteristics.

Furthermore, Chuba's or Barondes's PBS-suspended bacterial host cells comprising the above-identified nucleotide sequence would inherently serve as immunogenic compositions. The teachings of Chuba *et al.* or Barondess *et al.* (1990) anticipate the instant claims. Harlow *et al.* is **not** used as a secondary reference in combination with Chuba *et al.* or Barondess *et al.* (1990), but rather is used to show that every element of the claimed subject matter is disclosed by Chuba *et al.* or Barondess *et al.* with the unrecited limitation(s) being inherent in view of what is well known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Claims 37-40, 43 and 67 are anticipated by Chuba *et al.* or Barondess *et al.* (1990).

Remarks

25) Claims 30-33, 37-44 and 67 stand rejected. Claim 45 stands objected to as being dependent from a rejected claim.

It is noted that claim 38 includes the confusing limitation: 'the nucleic acid molecule comprises a vector' as opposed --the nucleic acid molecule is comprised in a vector--.

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26) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

27) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242 which receives papers 24 hours a day, seven days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

28) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached Monday through Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April, 2003

S. DEVI, PH.D.
PRIMARY EXAMINER